DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

January 4, 2001

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Bradley N. Grossman, President
American Supplement Technologies
1325 West 21st Street
Tempe, AZ 85282

W/L 21-01

Dear Mr. Grossman:

During an inspection of your dietary supplement contract manufacturing facility located at 2009 East 5th Street in Tempe, AZ conducted March 29 to March 30, 2000, we found that you manufactured and distributed [redacted] under the [redacted] label. A sample of this product (Sample number 82056) was collected and analyzed by the Food and Drug Administration.

Our analysis revealed that the above product coded [redacted] is adulterated within the meaning of 402(b)(1) in that a valuable constituent (Vitamin B6) has been omitted or abstracted therefrom. The product is labeled to contain 5 mg or 250% of the USRDA in six tablets. Our analysis of this product was unable to detect the presence of any Vitamin B6 in six tablets.

This product is misbranded within the meaning of 403(a)(1) because the product labeling is false and misleading in that it declares the ingredient Vitamin B6 which FDA analysis was unable to detect.

Furthermore, the product is misbranded within the meaning of section 403(q)(5)(F) of the Act in that the label fails to bear nutrition labeling ("Supplement Facts" panel), which is required under 21 CFR 101.36 and is not exempt from this requirement.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

We collected and analyzed a sample of '[redacted]' coded [redacted] under the [redacted] label in July of 1999 that was also found to be adulterated and misbranded because it was found to contain approximately 77% of label claim for Vitamin B12. During the March 2000 inspection, you were notified of this result.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Also include in your response your plans with regard to all [redacted] coded [redacted] currently in distribution. Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Alonza E. Cruse
District Director